Request of a change of Classification for "Breastlight" a Transilluminator for breast evaluation (21 CFR 892.1990) by PWB Health Ltd, UK.

Comment with respect to Docket No FDA-2010-N0412 and RIN number 0910-AG51

PWB Health Ltd, Polaroid Building, Vale of Leven Industrial Estate, Dumbarton, UK, G82 3PW request a change in classification for their Breastlight product. This products stated intended purpose is "as an aid to breast self examination" and as an addition to the woman's normal breast health routine. See www.breastlight.com

This product is classified, in a number of countries throughout the world, as a Class 1 medical device. In these countries and areas including Canada and the European Union, the product has been already placed on the market. As a result, we have accumulated a growing body of evidence from structured user trials, Ethics approved clinical trials, end user feedback, product design and safety information confirming the products' effectiveness and safety. We request that the FDA consider a home use, non diagnostic breast transilluminators products, such as Breastlight, whose intended purpose is as an aid to breast self examination is re-classified as a class 1 medical device in the United States.

The initial specific concerns raised by the FDA (Obstetrics and Gynaecology Devices Panel) about breast transilluminators, in general, were as follows :-
-Electrical Shock Risk
-Optical Radiation Risk
-Potential for missed or delayed diagnosis (false reassurance from false negative) or unnecessary anxiety from false positive.

Our risk assessment , carried out in accordance with ISO 14971, had already highlighted these potential risks and we have eliminated / mitigated these risks with our Breastlight product as follows:
Electrical shock risk – the Breastlight is designed as a low power, low voltage, internal battery powered device. The maximum voltage in the device is 9 volts and is therefore safe.
Optical Radiation Risk – The Breastlight is designed to be eye safe at maximum power setting. This has been designed and tested as a Class 1 LED product to IEC/EN60825-1(2001). In addition the Breastlight has a patented capacitive switch operation which only triggers the "bright light mode" when in full contact with skin and therefore does not allow the user to directly view the LEDs at full power.
Potential for Missed or delayed diagnosis (false reassurance from false negative) or anxiety from false positive – As part of our Post Marketing Surveillance responsibilities under the European Medical Device Directive, we have carried out both Ethics committee approved clinical trials and user trials to quantify this risk.

- The clinical trial results in the UK indicate that the Breastlight effectiveness "correlates well in terms of sensitivity and specificity when compared to established imaging techniques such as Ultrasound and Mammography. This was also the case when compared to histology/cytology.". "Breastlight performs well against cytological/histological findings; 12 of 18 malignant tumours were detected using Breastlight giving a sensitivity of 67% (95% confidence interval 41% to 87%). 240 of 282 breasts with no malignancy found were correctly identified as negative giving a specificity of 85% (95% confidence interval 80% to 89%). As a comparison X Ray Mammography is the current "gold standard" and considered to be 60-90% accurate depending on age of patient.
- The user trial results of 1087 users in the UK indicate that using the current packaging, Instructions for use and DVD convey an appropriate level of caution in interpretation of the results, does not adversely affect screening behaviour and does not appear to have high false-alarm rate.

FDA-2010-N-0412

C

- An Ethics approved trial on 45 patients in the UK tracked usage of Breastlight and attitudes towards breast health over a four month period. The majority of participants found the device easy to use and helpful in their self examination routines. There was no evidence of false reassurance or unnecessary anxiety, indeed the observed change in behaviour was an increase in breast self examination frequency. The majority of participants reported an increased understanding about breast health and confidence in their ability to detect abnormalities.

The FDA's original conclusion that "that there were no published studies or clinical data demonstrating the safety and effectiveness of the device" may be reviewed by taking account of the studies conducted and referred to above.

We would acknowledge that there is potential for misuse of Breast Transilluminators if they are sold as or give the impression of being suitable as an alternative to x ray mammography and regular clinical breast examinations. We have mitigated this risk with the Breastlight product by introducing clear instructions on our Instructions for Use, Packaging, DVD and web page that indicate:
"Breastlight should not be seen as a substitute for mammogram screening or a replacement for general breast awareness – both looking AND feeling"
"Breastlight is not intended for use as a diagnostic device. It is not capable of detecting all sizes, positions and types of breast abnormalities."
"If you notice any changes when using Breastlight or from your usual breast awareness routing, you should visit your doctor as soon as possible."
"Breastlight may highlight a potential abnormality that subsequently turns out to be normal or requires minimal medical intervention.... We would recommend that any suspicious signs are investigated by a doctor.
We feel that appropriate and agreed wording of packaging, advertising, Instructions for Use, DVD's web pages **can be agreed with the FDA** in order to mitigate this risk and to ensure the proper safe and effective use of this device.

Finally, the identified risks and the mitigation of risks above should be considered alongside the positive benefits of the device. Our clinical trials and user trials indicate the following benefits:

- increased frequency of checking,
- increased confidence in checking,
- increased number of women carrying out checks,
- increase in confidence that person is carrying out an effective examination,
- detection of non palpable cancers between regular scheduled mammogram,
- positive experience by women with inherently lumpy breasts who otherwise would not self check.

We would be happy to share detailed trial results, measurements or product details on any of the above topics in support of this reclassification request.

We trust that our assessment and summary review of the safety and effectiveness of our product Breastlight be given appropriate consideration and weighting when FDA determine the potential for reclassifying Transilluminators for breast evaluation (21 CFR 892.1990). We strongly support the view that the appropriate and ethical use of these products do have a defined benefit over risk, as demonstrated by our clinical trial results, and re-affirm our view that products such as Breastlight which act as an aid to breast examination be reclassified in the United States as a Class 1 (general controls) medical device.

If you require any additional information or details from our company, please do not hesitate to contact me.

Russell Overend
Regulatory Affairs Manager
PWB Health Ltd
Polaroid Building
Vale of Leven Industrial Estate
Dumbarton
UK
G82 3PW
Tel – 01144 1389714091
E mail russell.overend@pwbhealth.com